REMARKS

The Final Office Action of December 31, 2003 and Advisory Action of March 15, 2004 have been reviewed and their contents carefully noted. Reconsideration of this case, as amended, is requested. Claims 2 through 11, 13 through 18, and 20 through 25 remain in this case, claims 2, 5, 6, 9, 10, 11, 13, 16, 17, 18, 20, 23, 24, and 25 being amended and claims 1, 12, and 19 being cancelled by this response. No new matter has been added.

Preliminary Comments

The claims were amended as follows:

Claims 10, 18, and 25 were rewritten in independent form.

Claims 2, 5, 6, 9, and 11 were amended to depend from newly independent claim 10.

Claims 13, 16, and 17 were amended to depend from newly independent claim 18.

Claims 20, 23, and 24 were amended to depend from newly independent claim 25.

Rejections under 35 U.S.C. §103

Claims 1-3, 5-7, 9-14, 16-21, and 23-25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker *et al.* (U.S. Patent No. 6,269,810) in view of Gilmore *et al.* (U.S. Patent No. 5,931,160).

In rejecting claims 1-3, 5-7, 9-14, 16-21, and 23-25, the office action acknowledges that Brooker does not teach or suggest "adjusting of a respiratory flow or tidal volume of the inhalation device" (Final Office Action, dated 12/31/03, page 3, lines 15-16). Gilmore does not provide what Brooker lacks.

As already acknowledged by the Examiner, Brooker *et al.* (U.S. Patent No. 6,269,810) does not teach or suggest "adjusting of a respiratory flow or tidal volume" (Final Office Action,

dated 12/31/03, page 3, lines 15-16). However, this is an essential aspect in individualizing the inhalation for an individual patient. Only with the adjustment of the respiratory flow or the tidal volume based on the individual patient parameters and/or aerosol parameters for the inhalation is it possible for sufficient drug to be delivered to the lung. In this regard it is not decisive what is dispensed by the inhalation device but rather what is actually transported to the lung, i.e., what amount of the dispensed aerosol reaches the lung. This, of course, strongly depends on the kind of aerosol that is to be inhaled, and on the individual patient parameters (for example, lung volume, inhaling rate, inhaling volume etc.) but not so much on the inhalation device itself. This aspect was clearly not recognized by Brooker *et al.*, and the applicants claim to be the first who realized that an individualization of the inhalation is necessary, especially for expensive drugs or drugs where it is of utmost importance that no over-dosage occurs. Furthermore, applicants claim to be the first to realize that such an individualization can be achieved on the basis of the individual patient parameters and/or aerosol parameters, as laid out in the new independent claims.

In clear contrast thereto, Brooker *et al.* is only concerned with the drug dosage, i.e., is focused on the dosage of drug that is dispensed by the inhalation device so that the drug dosage that actually reaches the lung varies widely.

As regards Gilmore *et al.* (U.S. Patent No. 5,931,160), applicants again point out that a ventilator control system is totally remote from an inhalation system. First, with a ventilator system, quite different volumes and flows are used. The volumes and flows with a ventilator system are quite higher than with an inhalation device. Thus, a ventilator system is not at all suitable for an inhalation. With a ventilator system, it is only important that sufficient oxygen reaches the lung but a specific dosage of an aerosol like in an inhalation device is of no importance with a ventilation system. Thus, inhalation devices have a different focus. Moreover, inhalation devices according to the present invention may be used by the patients alone without the necessity of having a medical doctor being present during the inhalation. Oh the other hand, with a ventilator system, it is always required that a medical doctor starts and monitors the ventilation to guarantee that in extreme cases the patient does not pass away.

Due to these differences, the Examiner's statement in the advisory action that "Gilmore has a controller which receives patient protocols or parameters and causes flow and volume changes to an **inhalation device** to provide a patient specific ventilation regime related to the protocol" (Advisory Action, dated 3/15/04, continuation sheet, lines 6-8, emphasis added) is not correct. A ventilator system is not an inhalation device. Thus, due to the different focus of an inhalation device compared to ventilator systems, a person of ordinary skill in the art of inhalation devices would never consider prior art relating to ventilator systems.

Moreover, the control system that is suggested by Gilmore *et al.* is not comparable to the adjusting means of the new independent claims. According to Gilmore, the controller receives patient protocols during the ventilation in order eventually to modify the ventilation, for example, in case there is spontaneous respiratory muscle activity of the patient. Furthermore, the system of Gilmore *et al.* stores a plurality of patient protocols in a data base, and a processor simultaneously adjusts controls within the ventilator pneumatic system using the selected patient protocol. This seems to suggest that a breathing protocol is recorded for a certain time interval, and that the subsequent ventilation is then based on this previously recorded protocol. While the breathing protocol was recorded, if the breathing pattern changed, this is then probably reflected during the ventilation process in that the ventilation is adjusted to the change in the breathing pattern. On the other hand, according to the present invention, the individual patient parameters and/or aerosol parameters for the inhalation are pre-set, and stored on a storage medium, and are later used by the inhalation device for inhalation. If the patient's pulmonary function changes, the inhalation device may be re-set to the changed basic condition (see page 5 of the specification, item 8 in line 18).

Gilmore does not even relate to an inhalation device, let alone to a device for the controlled inhalation of therapeutic aerosols during breathing maneuvers as claimed in the amended claims. Rather, this reference relates to a ventilator control system and method. Ventilator control systems are provided for totally different purposes, namely to assist patients in breathing by ensuring that sufficient oxygen is supplied to the lungs of the patient and that the exhaled air is properly removed. To meet this need, ventilator control systems determine the inhalation volume and the breathing frequency of the patient such that sufficient oxygen is

supplied to the patient. If these parameters were not determined appropriately, there is the risk that the patient might suffocate.

Merely to serve this purpose, Gilmore *et al.* suggest an improved ventilator control system for controlling a ventilator pneumatic system using historical patient data stored in a database. The ventilator control system includes a database, which stores a plurality of patient protocols, each patient protocol comprising a set of breath parameters and patient data. A user interface is electrically coupled to the database for selecting a patient protocol. A processor is electrically coupled to the user interface for receiving the selected patient protocol. The processor simultaneously adjusts controls within the ventilator pneumatic system using the selected patient protocol (US 5,931,160, column 5, lines 23-33). Furthermore, Gilmore *et al.* suggest a method for providing an assisted phase of a breath to a patient connected to such a ventilator pneumatic system. Such a method includes the step of monitoring an accumulated volume of gas inhaled by the patient resulting from the particular spontaneous respiratory muscle activity. More specifically, the monitoring step further includes measuring a flow of gas inhaled by the patient resulting from the patient's spontaneous respiratory muscle activity, and integrating the flow to provide the measured accumulated volume (US 5,931,160, column 5, line 65 - column 6, line 7).

In clear contrast with Gilmore, a patient using the claimed inhalation devices breathes normally and does not need any assistance for inhalation and exhalation of air. Ventilator systems as suggested by Gilmore *et al.* merely ensure that sufficient air is supplied to the lungs of the patient, whereas with an inhalation device, sufficient air is automatically inhaled by the **healthy** patient. Inhalation devices only assist in transporting an aerosol **in addition to the air** to the lungs of the patient.

In particular, the present invention not only ensures that aerosol is transported to the lungs of the patient in addition to air (i.e., oxygen) but particularly ensures that the appropriate amount of the drug is transported to the lungs, and even ensures that the drug is deposited at the necessary target area in the lungs (i.e., at the bronchi or the alveolus). This is achieved according to the present invention in that the respiratory flow and/or a tidal volume of the inhalation device is adjusted so that an individual aerosol dosage is adjustable on the basis of the predetermined

individual patient parameters and/or aerosol parameters. Thus, with the present invention, the desired amount of drug can be transported to the desired treatment area in the lungs. This may also be made dependent on the pharmacokinetics of the used drug.

Although Gilmore suggests controlling the ventilator pneumatic system using a selected patient protocol, Gilmore *et al.* clearly do not suggest adjusting a respiratory flow and/or a tidal volume of an inhalation device in order to adjust an individual aerosol dosage on the basis of predetermined individual patient parameters and/or aerosol parameters in order to provide a controlled inhalation of a therapeutic aerosol during a breathing maneuver.

In other words, the same feature missing from Brooker is likewise missing from Gilmore. Gilmore does not provide what Brooker lacks. Also, an ordinary worker interested in metered inhalation would reject Gilmore's ventilator as cumbersome, expensive, and impractical. A patient who is able to breathe unaided would not be put on a ventilator to accomplish drug inhalation.

Starting out from Brooker *et al.*, there is no teaching or suggestion in Gilmore *et al.* to motivate one of ordinary skill in the art to modify the control of the inhalation such that individual patient parameters and/or aerosol parameters are used for adjusting the respiratory flow and the tidal volume of the inhalation device to provide an individual aerosol doses to the patient. Neither Brooker *et al.* nor Gilmore *et al.* teach or suggest a recognition of the problem underlying the present invention. There is no hint in Gilmore *et al.* towards the problem underlying the present invention, i.e., the individualized inhalation.

For these reasons, even the combination of the teaching of Brooker *et al.* and Gilmore *et al.* does not lead a skilled person to an inhalation device according to the present invention. Since Gilmore *et al.* do not suggest the adjustment of respiratory flow and/or the tidal volume of the inhalation device in order to provide a controlled individualized inhalation of therapeutic aerosols, it would not be obvious in view of Gilmore *et al.* to provide Brooker *et al.* with such an individualized adjustment of these parameters.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 4, 8, 15, and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker *et al.* (U.S. Patent No. 6,269,810) in view of Gilmore *et al.* (U.S. Patent No. 5,931,160) and further in view of Willemot *et al.* (U.S. Patent No. 5,560,353). The arguments regarding the nonobviousness of claims 10, 18, and 25 are incorporated herein by reference.

In rejecting claims 4, 8, 15, and 22, the Final Office Action additionally cited Willemot for teaching a keyboard and memory card. Willemot does not provide what Brooker and Gilmore lack, namely, adjustment of respiratory flow and/or tidal volume of the inhalation device.

Advantages of the claimed subject matter over the cited art serve as further evidence of unobviousness. These advantages include that the inhalation device according to the present invention is a substantial improvement over conventional inhalation devices. The provision of individual patient parameters and/or aerosol parameters leads to the advantage that these can be provided on a storage medium regardless of the specific inhalation device that is used for inhalation. This allows optimization of the therapy for the patient. Furthermore, this improves safety for the patient because erroneous adjustment of the inhalation device is thus prevented.

Moreover, a clear need for the advantages provided by the claimed subject matter is shown in the enclosed copies of two publications from two journals relevant to the present technical field. These publications (*Journal of Aerosol Medicine*, Vol. 14, No. 3, 2001, page 388 and *The Aerosol Society: Drug Delivery to the Lungs XII*, page 23-26) emphasize the advantages that are related to the individualization of the aerosol inhalation in accordance with the present invention. It is now possible with the claimed invention to provide a pinpointed and more efficient deposition of the drug in the lung, which leads to a decrease of the amount of the necessary drug, which results in a substantial reduction in costs.

In the prior art it is impossible to adjust an inhalation device individually to the specific needs of a specific patient and to an individual drug. This is now possible with an inhalation device according to the present invention. The individualization of the deposition of drugs is becoming more and more important, and the pharmaceutical industry is even now in the process of developing new strategies for providing individualized drug combinations for each specific patient.

Commercial success of the claimed invention additionally establishes its nonobviousness from the cited art. For example, The German company Bayer AG is currently developing a new drug for treatment of a specific type of lung emphysema. Since such patients suffer from severe lung damage, and since the function of the lung is continuously decreasing, it is only possible by means of an individualized inhalation to deposit a sufficient amount of drug in reasonable time into the lungs of the patient. The inhalation device according to the present invention is used by Bayer AG for the deposition of this new drug. The details of the corporation agreement between the present applicant and Bayer AG are confidential, but Bayer AG has already publicly announced that there is cooperation between the present applicants and Bayer AG in this field.

For these reasons, applicants believe that their invention as claimed in the new claims is patentable over the prior art.

Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

Applicant believes the claims, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

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